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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/819,091	02/16/2000	Yongwei Cao	16517.124	5196

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EXAMINER	
MYERS, CARLA J	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 03/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/819,091	CAO ET AL.	
	Examiner	Art Unit	
	Carla Myers	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 8-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 8-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: Notice of Withdrawal from Issue

1. The allowability of claims 1-3 and 8-11 is withdrawn. As indicated in the letter of February 2, 2004, prosecution in this application is being re-opened. Upon further consideration, the following grounds of rejection are being applied. This action is made non-final.

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The pending claims have been reviewed in light of the Utility Examination Guidelines and Guidelines for Examination of Patent Applications under 35 U.S.C. 112, first paragraph, "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1092-1111, Friday, January 5, 2001.

The examiner is using the following definitions in evaluating the claims for utility.

"Specific" - A utility that is *specific* to the subject matter claimed. This contrasts with a *general* utility that would be applicable to the broad class of the invention.

"Substantial" - A utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities.

"Credible" - Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record that is probative of the applicant's assertions. That is, the assertion is an inherently unbelievable undertaking or involves implausible scientific principles.

"Well-established" - a specific, substantial, and credible utility which is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art.

3. Claims 1-3 and 8-11 are rejected under 35 U.S.C. 101 because the claimed invention lacks a credible, substantial, specific or well-established utility.

The claims are drawn to substantially purified nucleic acids having the sequence of SEQ ID NO: 1, nucleic acids capable of specifically hybridizing with SEQ ID NO: 1, nucleic acids having 90% to 100% complementarity to SEQ ID NO: 1, and proteins encoded by a nucleic acid capable of specifically hybridizing with SEQ ID NO: 1. The claimed nucleic acids and proteins are not supported by either a specific and substantial asserted utility or a well-established utility. The specification fails to provide objective evidence of any activity for the claimed nucleic acids and proteins.

The specification (Table 1) teaches that the nucleic acid of SEQ ID NO: 1 was isolated from Arabidopsis thaliana. This nucleic acid encodes for an "unknown protein with Src homology 3 (SH3) domain profile." However, the specification has not established that the presence of the SH3 domain profile imparts a specific biological activity to the encoded protein. The specification (page 39) states that the claimed nucleic acids can be used to obtain other nucleic acids from the same species or to isolate homologous nucleic acids from other species. However, such uses lack a specific and substantial utility. Such uses allow only for the identification and analysis of other nucleic acids. Because a utility has not been established for the present nucleic acid, the use of this nucleic acid to search for additional nucleic acids does not constitute a "real world" context of use. The specification (page 39-40) further contemplates that the nucleic acid of SEQ ID NO: 1 can be used for mapping studies, linkage analysis, constructing of transgenic plants, screening for traits or screening for polymorphisms. However, these uses are applicable to a broad class of molecules since all plant nucleic acids could be used for these purposes. Thereby these uses are

general and do not constitute a specific utility. While the use of the nucleic acid of SEQ ID NO: 1 in the disclosed methods may eventually lead one to the identification of useful traits or specific polymorphisms or may eventually allow for the generation of transgenic plants, such uses constitute further research and experimentation and do not provide a readily-available, specific and substantial real-world use. It is further asserted that the nucleic acid of SEQ ID NO: 1 can be used for antisense methods to "prevent or reduce gene function" (see page 79 of the specification). However, since it is unclear as to the activity of the nucleic acid of SEQ ID NO: 1 and the protein encoded by SEQ ID NO: 1, the use of the claimed nucleic acids to block or prevent an unknown function constitutes further research. Thereby, the use of the claimed nucleic acids for antisense methods does not provide a substantial, real world use for the claimed nucleic acids. It is contemplated that the nucleic acid of SEQ ID NO: 1 can be used to synthesize protein, which could then be used in conducting further research to characterize the protein. However, the need for such research clearly indicates that the protein is not provided in a form that can be currently utilized for a real world purpose. Identifying and studying the properties of a protein or the mechanisms in which the protein is involved does not constitute a specific and substantial utility. The specification also suggests that the claimed proteins could be used to generate antibodies which could be used for detection purposes. Again, because a utility has not been established for the protein, use of the protein to generate antibodies to isolate and study proteins constitutes a research project and does not provide a specific and substantial utility. As stated in *Brenner v. Manson,* 383 US 519, 535-536, 148 USPQ 689, 696 (1966), "a patent is not

a hunting license. It is not a reward for the search, but compensation for its successful conclusion." In the present case, Applicants have not established that the claimed nucleic acid encodes for a protein with a specific biological activity, or that the nucleic acid or protein could be used to identify a particular trait or to detect a particular polymorphism of known function. Accordingly, the claimed invention is not supported by either a specific or substantial asserted utility or a well-established utility. Applicant is directed to the Utility Examination Guidelines, Federal Register, Vol. 66, No. 4, pages 1092-1099, Friday January 5, 2001.

Claim Rejections - 35 USC § 112

4. Claims 1-3 and 8-11 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention.

Furthermore, the specification has not adequately taught one of skill in the art how to use nucleic acids that are capable of specifically hybridizing with the nucleic acid of SEQ I D NO: 1 or which comprise a nucleic acid which has 90%-100% identity with SEQ ID NO: 1. The specification does not clearly define what is intended to be encompassed by nucleic acids which "specifically hybridize" with SEQ ID NO: 1. The specification (page 19) states that "(i)n a preferred embodiment," the claimed nucleic acids will specifically hybridize with SEQ ID NO: 1 under moderately stringent hybridization conditions. However, it is unclear as to what is intended to be

encompassed by nucleic acids which "specifically hybridize" with SEQ ID NO: 1. Claim 2 does not clarify whether the claimed nucleic acid hybridizes only to SEQ ID NO: 1 and not to any other nucleic acids and / or does not clearly set forth the conditions of hybridization at which this "specificity" is achieved. Claims 2 and 3 also fail to provide a length limitation for the nucleic acid or for the protein encoded by the nucleic acid. Thereby, the nucleic acids encompass fragments that share, for example 60%, 70% etc complementarity with SEQ ID NO: 1, and contain flanking sequences of unspecified length and identity. Further, claims 8-11 encompass nucleic acids comprising a nucleic acid sequence having 90%-100% identity with a nucleic acid sequence of SEQ ID NO: 1. The claims do not clarify whether such nucleic acids share identity over the full length of SEQ ID NO: 1. Thereby, it appears that claims 8-11 encompass nucleic acids containing fragments having 90%-100% identity with a fragment of SEQ ID NO: 1 and flanked by sequences of unspecified length and identity. Accordingly, the claims include nucleic acids and proteins from other species, naturally-occurring and non-naturally occurring mutated nucleic acids, allelic variants, and splice variants. The specification has not adequately taught one of skill in the art how to use these nucleic acids. The specification has not established that species within this genus of nucleic acids and proteins have any particular biological activity and the specification has not provided sufficient guidance as to how to use the genus of claimed nucleic acids without undue experimentation.

5. Claims 2-3 and 8-11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to

reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The claims are drawn to substantially purified nucleic acids capable of specifically hybridizing with SEQ ID NO: 1, nucleic acids having 90% to 100% complementarity to SEQ ID NO: 1, and proteins encoded by a nucleic acid capable of specifically hybridizing with SEQ ID NO: 1. The specification teaches that SEQ ID NO: 1 is a nucleic acid isolated from Arabidopsis thaliana. Nucleic acids consisting of SEQ ID NO: 1 and proteins encoded by SEQ ID NO: 1 meet the written description requirements. However, the specification does not provide an adequate written description of the claimed genus of nucleic acids that specifically hybridize with SEQ ID NO: 1 or which having 90-99% identity with SEQ ID NO: 1. With respect to claims 2 and 3, the specification does not clearly define what is intended to be encompassed by nucleic acids which "specifically hybridize" with SEQ ID NO: 1. The specification (page 19) states that "(i)n a preferred embodiment," the claimed nucleic acids will specifically hybridize with SEQ ID NO: 1 under moderately stringent hybridization conditions. However, it is unclear as to what is intended to be encompassed by nucleic acids which "specifically hybridize" with SEQ ID NO: 1. Claim 2 does not clarify whether the claimed nucleic acid hybridizes only to SEQ ID NO: 1 and not to any other nucleic acids and / or does not clearly set forth the conditions of hybridization at which this "specificity" is achieved. Claims 2 and 3 also fail to provide a length limitation for the nucleic acid or for the protein encoded by the nucleic acid. Further, claims 8-11 encompass nucleic acids

comprising a nucleic acid sequence having 90%-100% identity with a nucleic acid sequence of SEQ ID NO: 1. The claims do not clarify whether such nucleic acids share identity over the full length of SEQ ID NO: 1. Thereby, it appears that claims 8-11 encompass nucleic acids containing fragments having 90%-100% identity with a fragment of SEQ ID NO: 1 and flanked by sequences of unspecified length and identity. Accordingly, the claims include nucleic acids and proteins from other species, naturally-occurring and non-naturally occurring mutated nucleic acids, allelic variants, and splice variants and fragments of said nucleic acids. However, the specification does not exemplify any specific nucleic acids that specifically hybridize with SEQ ID NO: 1 or which have 90-99% identity with SEQ ID NO: 1.

The claims define the nucleic acids and proteins in terms of their structure, but do not define the nucleic acids in terms of their functional properties. Accordingly, the claims are inclusive of nucleic acid molecules and proteins which have distinct biological activities from the nucleic acid of SEQ ID NO: 1 and the protein encoding by SEQ ID NO: 1. The specification has not clearly set forth a biological activity for the claimed nucleic acid or protein and has not exemplified any specific nucleic acids or proteins which have 90-99% identity with SEQ ID NO: 1 or the protein encoded thereby and which have a specific biological activity that is distinct from SEQ ID NO: 1.

The claims do not require that the nucleic acids share sequence identity over the full length of the molecule or that that nucleic acids which "specifically hybridize" with SEQ ID NO: 1 are of the same length as SEQ ID NO: 1. Further, the claims recite the open claim language "having." Thereby, the claims include nucleic acid fragments

having 90-100% identity with SEQ ID NO: 1 wherein the sequences flanking said fragments are undefined. Thereby, the claims read on additional splice variants and homologues which differ significantly from SEQ ID NO: 1 in terms of their structure and function.

The general knowledge in the art concerning homologues, mutants, allelic and splice variants does not provide any indication of how modification of the sequence of SEQ ID NO: 1 will effect the functional properties of SEQ ID NO: 1 and the protein encoded by SEQ ID NO: 1. The structure and function of one molecule does not provide guidance as to the structure and function of other molecules. Therefore, the description of one molecule (SEQ ID NO: 1) is not representative of a genus of homologues, splice, mutant and allelic variants of SEQ ID NO: 1 having unspecified functional activities different from that of SEQ ID NO: 1. *Vas-Cath Inc. V. Mahurkar*, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed". Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. In *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An

adequate written description of a DNA...'requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention". The limited information provided in the specification is not deemed sufficient to reasonably convey to one of skill in the art that Applicants were in possession of the claimed homologues, mutants, allelic and splice variants of SEQ ID NO: 1 and proteins encoded thereby. Therefore, the written description requirement has not been satisfied for the claims as they are broadly written. Applicants attention is drawn to the Guidelines for the Examination of Patent Applications under 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2 and 3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2 and 3 are indefinite over the recitation of "capable of specifically hybridizing." Capability is a latent characteristic and the claims do not set forth the conditions under which the capacity to hybridize is to be determined. The skilled artisan cannot determine what is encompassed by the claimed invention because the claims do not set forth the conditions for determining whether the nucleic acid has or has not hybridized. It is noted that the specification (page 19) states that "(i)n a preferred embodiment," the claimed nucleic acids will specifically hybridize with SEQ ID NO: 1

under moderately stringent hybridization conditions. However, this represents only a preferred embodiment of the claimed invention. The limitation of "moderately stringent hybridization conditions" is not read into the claims. Further, the specification has not clearly defined what constitutes "moderately stringent hybridization conditions." It is unclear as to what is intended to be meant by "specifically hybridize." For example, it is unclear as to whether such nucleic acids hybridize only to SEQ ID NO: 1 (and thereby are fully complementary to SEQ ID NO: 1) or if such nucleic acids also hybridize with variants of SEQ ID NO: 1 (e.g., variants having 99%, 98%, 95%, 90%, 70% etc identity with SEQ ID NO: 1). In the later case, there are no specific teachings provided in the specification to indicate the cut-off point at which the nucleic acid no longer specifically hybridizes to SEQ ID NO: 1. If the claimed nucleic acid is capable of hybridizing with a nucleic acid that differs from SEQ ID NO: 1 by even 1 nucleotide, then such nucleic acids are not truly specific for SEQ ID NO: 1. Because the phrase "specifically hybridizes" is not clearly defined in the specification or art, one cannot determine the meets and bounds of the claimed subject matter.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (571) 272-0747. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (571)-272-0782.

Papers related to this application may be faxed to Group 1634 via the PTO Fax Center using the fax number (703)-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status

information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Carla Myers
March 8, 2004

CARLA J. MYERS
PRIMARY EXAMINER